Health-Based Advisory Levels for Homeland Security Use

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Abstract

The Homeland Security Presidential Directive No.5 requires Federal agencies to develop national emergency preparedness guidelines for terrorist incidents or natural disasters. However, for many chemical and biological agents, health-based exposure guidelines are not available to identify appropriate levels for re-occupation of buildings or reuse of drinking water. Hence, the U.S. EPA National Homeland Security Research Center (NHSRC), in collaboration with the Department of Energy Argonne National Laboratory and Oak Ridge National Laboratory, are developing health-based provisional advisory levels (PALs). PALs are threshold exposure limits for the general public, including susceptible and sensitive subpopulations. They can be applied for national emergency programs, community planning, and public health protection. Specifically, they are applicable for establishing health-based criteria for re-entry into buildings, reuse of drinking water, and cleanup of contaminated facilities. Scientific judgment and credible data are used to identify appropriate toxicity endpoints for establishing the point of departure (POD) for developing PAL values. They are derived for acute (24 hours), short-term (>1–30 days), and longer-term (>30 days to 2 years) oral and inhalation exposures to industrial chemicals, biologicals, radionuclides, and chemical warfare agents. The three levels (PAL1, PAL2, and PAL3) for each exposure period are distinguished by the degree of severity of toxic effects. Draft PAL values are evaluated by an EPA working group, and by independent multidisciplinary expert panels to ensure credibility and acceptance in the scientific community.

Background

The Need for Provisional Advisory Levels (PALs)

- **Existing exposure guidelines don't completely address Homeland Security preparedness**
  - What levels of chemical/biological agents must be detected? Will capabilities adequately support health risk-based decisions?
  - What are potential breakdown products in air and water? Are they adequately characterized in environmental media?
  - Are potential health hazards identified and addressed?
- **Existing exposure guidelines don't completely address Homeland Security emergency response**
  - When should people be evacuated?
  - When should people re-enter buildings or re-use water?
  - What potential health effects could occur at different exposure durations?

PAL Program: An Interagency Collaboration	
A combined effort of EPA and DOE	➢ National Homeland Security Research Center (NHSRC) ➢ Argonne National Laboratory (ANL) ➢ Oak Ridge National Laboratory (ORNL)
Participating EPA Program Offices and Centers	➢ Office of Pollution Prevention and Toxics (OPPT) ➢ National Center for Environmental Assessment (NCEA) ➢ Office of Water (OW) ➢ Office of Solid Waste & Emergency Response (OSWER) – National Decontamination Team

What are PALs?

- Threshold exposure limits for general public, applicable to national emergency programs, community planning, and response
- Provide exposure guidelines for industrial chemicals, biologicals, radionuclides, and chemical warfare agents
- PALs are for acute (24 hours), short-term (>1 to 30 days), and longer-term (>30 days to 2 years) exposures to air and water
- Three exposure levels (PAL 1, PAL 2, and PAL 3), distinguished by degree of severity of toxic effects

Scope and Purpose of PALs

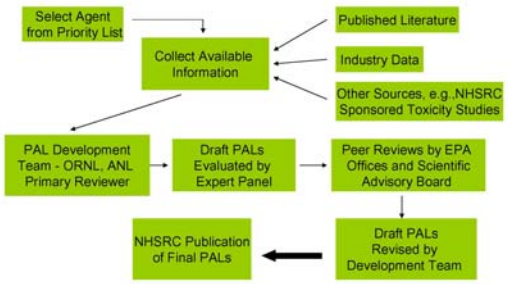
- Initial work is focused on priority chemicals including warfare agents
- Fill gaps of other exposure values (e.g., AEGL, ERPG, MRL, etc.)
- Provide health-risk based levels for threat assessment scenarios
- Develop approach for public protection in emergency situations
- Community planning for terrorist incidents and natural disasters
- Establish criteria for health-protective actions:
  - Re-entry into affected areas
  - Reuse of drinking water
  - Cleanup of contaminated infrastructures

Definition of PAL Tiers

- **PAL 1** represents the continuous exposure concentration of a chemical, and important degradation products, in air or water above which changes from baseline of specific biomarkers or physiological responses could have adverse health effects in the general population. Concentrations below PAL 1 are not expected to be associated with clinically-significant effects. Increasingly greater concentrations above the PAL 1 value could cause progressively harmful effects in the general population, including all ages and sensitive subpopulations.
- **PAL 2** represents the continuous exposure concentration of a chemical, and important degradation products, in air or water above which serious, irreversible, or escape-impairing effects could result. Increasingly greater concentrations above the PAL 2 value could cause progressively harmful effects in the general population, including all ages and sensitive subpopulations.
- **PAL 3** represents the continuous exposure concentration of a chemical, and important degradation products, in air or water above which lethality in the general population, including all ages and sensitive subpopulations could occur.

Tier Level	Effect Threshold
PAL 3	Severe effects, lethality
PAL 2	Impaired ability to escape increasing severity of irreversible, serious long-lasting effects
PAL 1	Mild, transient, reversible effects, below baseline of specific biomarkers

PAL Development Process



Derivation of PAL Values

- Identification of critical effect: the response, consistent with the PAL tier level, which serves as the basis for deriving a specific PAL value.
- Identification of point-of-departure: actual dose, exposure concentration, or calculated benchmark and respective exposure duration associated with a critical effect. It is used quantitatively for deriving PAL values.
- Scientific judgment and credible data are used to identify appropriate health endpoints for establishing the point-of-departure.
- Exposure duration extrapolation using known methodologies.
- Application of appropriate UF/MF.

Summary: Major Application of PALs

- Protective action, re-entry into buildings, and use/reuse of selected resources.
- Situations include, but are not limited to transport/storage accidents, subversive activities, and natural disasters.
- Applicable at federal, state, and local levels.
- Use in homeland security efforts by public health and law enforcement agencies, emergency response agencies, water utilities, and national and regional EPA offices.